EXHIBIT 197

Janssen Pharmaceuticals Inc. Abuse and Diversion Detection Program

Prescribers of Concern

This "rough ideas" document is intended to provide a foundation for a white board type exercise to establish programs suitable for a small, dedicated sales team (contract sales organization) working with about 10,000 HCP's in the pain management space.

Goal – make sure the Company is marketing to the proper prescribers;

Secondary goal - to provide guidance and require the sales representatives to recognize/detect and report suspected abuse and suspected diversion by HCP's of Janssen products.

Jack Crowley
crowleyassoc@att.net

Janssen Abuse and Diversion Detection Program - Prescribers of Concern

Initial Rough Notes – ideas – whiteboard

July 23, 2013

I. Establish a Standard Operating Procedure and Training Program for the Analgesic Team; Make this a requirement - initial training and annual update.

Goal – make sure you are marketing to the proper prescribers;

It is also a goal to provide guidance and require the sales representatives to recognize/detect suspected abuse and suspected diversion by HCP's of Janssen products (Nucynta® Nucynta® ER; [Concerta®]; Duragesic®; Tylenol® with Codeine; Tylox®; - Ultracet®; Ultram®; Ultram® ER) or other related products like OxyContin; oxycodone IR, methadone, Dilaudid, hydromorphone, hydrocodone, etc.

II. SOP considerations and broad sample:

PURPOSE

The purpose of this SOP is to provide direction to the Field (Contract) Sales Organization in an effort to identify possible abuse or diversion of Company products.

PRINCIPLE

Janssen markets medications that are scheduled under the Controlled Substances Act, which are by definition subject to potential abuse and diversion. Sales representatives may encounter situations in the field, which may cause concern that Janssen products may be the subject of abuse or diversion and/or which indicate criminal activity may be occurring. Although representatives do not have access to prescribers' patient records and are not investigators, certain situations must be reported to the XXX Department to protect the interests of legitimate patients, prescribers and dispensers, and the Company.

PROCEDURE

In the event that a sales representative, in the course of his/her activities in the field, observes or learns about any of the situations described below, such activities are to be reported to the company by submitting a Report of Concern (may be called anything you would like) through the XXX call reporting system (call notes).

Note - This list of examples can be discussed and refined – most of this was gleaned from various DEA communications:

An apparent pattern of an excessive number of patients for the practice type. Examples include: on a consistent basis, a long line of patients waiting to get prescriptions; a waiting room filled to capacity or standing room only; patient contact with a prescriber that is typically extremely short or non-existent.

An atypical pattern of prescribing techniques or locations. Examples include repeated prescribing in atypical locations such as a car or a residence or at atypical times such as very late at night.

Information from a highly credible source or several sources (pharmacists, law enforcement, healthcare workers) that a healthcare professional or patients of a healthcare professional are diverting medication.

A prescriber writing a large number of prescriptions for patients who receive prescriptions and pay with cash; sometimes described as “cash and carry”. These practices often have patients who are very young – teens and early 20’s. This is not to be confused with co-pay payments of a nominal amount.

Sudden unexplained change in prescribing or dispensing patterns, not accounted for by changes in patient numbers or the practice.

Multiple allegations that patients from a given practice have overdosed on medications.

Repeated credible allegations that prescriber, dispenser, staff or patient has or is actively abusing medications.

Unlicensed individual is signing prescriptions or dispensing medications.

Large numbers of patients who travel hundreds of miles for their prescription without rational explanation. Numerous out-of-state license plates in the parking lot may suggest patients who have traveled lengthy distances.

Reports of frequent early requests for new prescriptions made long before the initial prescription would normally be completed.

Credible allegations that a healthcare professional is under active investigation related to abuse or diversion by any law enforcement or regulatory authority

A healthcare professional who moves his or her practice from one state to another on more than one occasion within a couple of years.

When the form is completed, the sales representative may simply press send and it will be delivered to a mailbox accessed by the XXX Department. By doing so, this will record the date and time of the initial report, and who has made the report. A member of the XXX Department will then contact the sales representative to follow up as soon as possible.

(HCP) REPORT FORM

Please note - these type reports are different than product complaints, and pharmacovigilance – adverse events - drug safety reports. Nevertheless, they could get mixed up or lost in the shuffle. You can use call notes, intranet forms, emails and even phone calls - company hotline, etc. Simply must create a system so you don't miss these.

Please notify the XXX Department using the HCP report email form. The sales representative can access this form on the XXX Intranet website by clicking on the file name "HCP Report". The sales representative will need to complete all of the fields on the form. No additional information should be sent other than what is requested. When the form has been completed, the sales representative may simply press send and it will be delivered to a mailbox accessed by the XXX Department. By doing so, this will record the date and time of the initial report. A member of the XXX Department will then contact the sales representative to follow up as soon as possible.

The representative should not discuss this report with anyone other than his or her manager and persons designated by the XXX Department. **The representative should not make further visits to the subject practice or healthcare professional until instructed to do so by the XXX Department.**

At the conclusion of the XXX Department's internal inquiry, the representative will be informed, in writing, with a copy to the District Manager and Regional Manager, whether to continue calling on the particular healthcare professional.

III. Establish a Standard Operating Procedure or Standard Business Practice for Handling and Conducting Internal Inquiries.

Examples:

In each instance in which the XXX office receives notification of a sales representative's or other field personnel's concern about a healthcare professional's conduct that may indicate abuse or diversion of Nucynta® ER or other controlled substances distributed by Janssen, the XXX office will follow the procedures outlined below. As each inquiry is fact-specific, the person handling the inquiry will adjust these procedures to accommodate the particular situation and respond appropriately to whatever information is learned during the inquiry. The outline below is not meant to be the minimum nor all inclusive of steps taken.

Consult with the individual who has made the report ("Reporting Individual").

Obtain pertinent personal and background information from the Reporting Individual.

Obtain full statement of the basis for the report as well as pertinent background information on the person who is subject of the report. Identify any other Janssen or CSO (Quintiles) employees or other persons who may have relevant information.

Instruct the field personnel or sales representative to cease calling on the healthcare professional.

Contact the reporting individual's immediate supervisor.

Obtain pertinent personal and background information from the supervisor.

Identify whether the supervisor has discussed the situation with the Reporting Individual and what if any additional relevant information the supervisor may have.

Query whether the supervisor is aware of any other Janssen or CSO (Quintiles) employees or other persons who may have relevant information.

If necessary or appropriate, contact additional supervisors or others who have been identified to obtain additional relevant information.

If the report relates to a healthcare professional visited by a Janssen/CSO sales representative, obtain and review call report history for the pertinent time frame. Maintain a copy in the files.

Obtain and review prescription history for all opioids or relevant market of substances for the healthcare professional for the pertinent time period. Maintain a copy in the files.

Consider whether additional sources of information should be consulted based on the nature of the report and the background of the healthcare professional or other person about whom the concern is raised.

Consult with others in the Janssen XXX Office who are involved with reviewing such reports and any other Janssen employees who may have information or insight that will assist in deciding how, if at all, to respond to the report. Janssen's (individual title or department) ultimately will make all decisions on what, if any, action should be taken based upon the report and the information learned during the internal inquiry.

Upon reaching a decision, prepare a brief written summary that documents the decision made and the basis for the decision. Maintain a file that relates to each report and contains any relevant materials reviewed during the inquiry.

Notify the Reporting Individual that the inquiry is complete and whether he/she should resume calling on the healthcare professional in question. Such notification will be in writing with a copy to the Reporting Individual's immediate supervisor. In instances where a sales representative has been instructed to cease calling on a healthcare professional, Janssen will notify Quintiles of its decision to do so.

The XXX Office will take whatever steps are deemed appropriate, including but not limited to, notifying regulatory or law enforcement authorities of Janssen's concern about the conduct of a particular healthcare professional or other person.

On a quarterly basis, or more frequently if desired, submit a summary of all reports received and the inquiries conducted (including backup documentation) for review by an Advisory Committee, who may make any recommendations that the Committee sees fit.

After the review above, XXX's office will take appropriate steps, if necessary.

IV. Maintain the "Cease Calling" List - and Patient Assistance Discontinuance.

V. Determine whether or not there is any synergy between what was learned during the inquiry and any retail pharmacies serviced by Janssen authorized distributors.

"Know your customers' customer" - Janssen Suspicious or Noteworthy Order Monitoring System and collaboration/mutual support with authorized distributors.

----------End of first rough draft 7/23/13----------